

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

LOULOU FOUNDATION

Plaintiff,

v.

PTC THERAPEUTICS, INC.

Defendant.

Civil Case No. \_\_\_\_\_

**COMPLAINT  
JURY TRIAL DEMANDED**

Plaintiff LouLou Foundation (“**LLF**” or “**Plaintiff**”), by and through its undersigned counsel, as and for its complaint against PTC Therapeutics, Inc. (“**PTC**” or “**Defendant**”) alleges as follows:

**NATURE OF THE ACTION**

1. This lawsuit concerns PTC’s breach of its payment obligations pursuant to a Collaboration Agreement (as defined below) entered into between LLF, PTC, and others. PTC failed to pay its agreed share of the funding amounts due to LLF under the Collaboration Agreement and has also violated its duty of good faith and fair dealing inherent in all contracts by manufacturing a belated and pretextual basis to justify its wrongful termination of the Collaboration Agreement.

2. LLF is a non-profit organization dedicated to combating CDKL5 Deficiency Disorder (“**CDD**”), a rare neurodevelopmental condition characterized by uncontrollable seizures from infancy into adulthood. On July 23, 2021, LLF entered into a contract (the “**Collaboration**

**Agreement**”) with PTC, a biomedical pharmaceutical company, along with six other companies<sup>1</sup> (the “**Pharmaceutical Companies**”), to undertake and fund an Endpoint Enabling Study of Cyclin-dependent kinase-like 5 Deficiency Disorder (the “**CANDID Study**” or “**Study**”).

3. Under the terms of the Collaboration Agreement, the Pharmaceutical Companies would provide funding to support the CANDID Study in exchange for access to and the ability to commercialize the resulting data. LLF was to serve as “sponsor” of the Study, and a committee comprised of one voting representative from LLF and one from each of the participating Pharmaceutical Companies (including PTC) (the “**Steering Committee**”) would oversee the Study and evaluate its results.

4. Under the Collaboration Agreement, the Pharmaceutical Companies were required to pay LLF the total amount of \$2,4000,000 upon execution and \$1,700,000 on each of January 15, 2022, July 1, 2022, July 1, 2023 and July 1, 2024, with the payments to be divided equally.

5. After making the payments due in January and July, 2022, PTC failed to make the payment due on July 1, 2023. LLF demanded payment. PTC failed to comply, and asked LLF to release it from further obligations under the Collaboration Agreement. LLF refused and informed PTC that it would be held to its contractual payment obligations.

6. In order to excuse its non-payment, on August 4, 2023, PTC purported to unilaterally terminate its participation in the Collaboration Agreement, citing LLF’s alleged failure to fulfill its responsibilities under the Collaboration Agreement and resulting anticipatory breach. PTC informed LLF that it “will advance no additional funds to the LouLou Foundation

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<sup>1</sup> The seven Pharmaceutical Companies that are parties to the Collaboration Agreement include PTC, Biogen Inc., Ultragenyx Pharmaceutical, Inc., Amicus Therapeutics, Inc., Marinus Pharmaceuticals, Inc., Zogenix, Inc. and Elaaj Bio AG (Collaboration Agreement §§ 1.20, 3.21).

in connection with this matter,” repudiating its obligation to make the payments due in 2023 and 2024. As explained below, this purported termination is not permitted by the Collaboration Agreement and is entirely pretextual. PTC thus remains bound by the Collaboration Agreement, and is therefore in breach of its payment obligations. Additionally, PTC’s unambiguous statement that will not make any further payments constitutes an anticipatory repudiation, for which LLF is entitled to immediate compensatory damages equal to all remaining funding amounts it agreed to pay pursuant to the Collaboration Agreement.

7. Furthermore, through its pretextual purported termination, PTC has violated the implied covenant of good faith and fair dealing inherent to all contracts under New York law.

### **THE PARTIES**

8. Plaintiff LouLou Foundation is a non-profit organization, headquartered and operating in the United Kingdom. Its mission is to advance research into the understanding and development of therapeutics for CDD.

9. Defendant PTC Therapeutics, Inc. is a biomedical company incorporated in Delaware with its principal place of business in New Jersey.

### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332. PTC Therapeutics is incorporated in Delaware with its principal place of business in New Jersey. LouLou Foundation is incorporated and operates in the United Kingdom. The amount in controversy exceeds the \$75,000 statutory minimum.

11. This Court has personal jurisdiction over PTC and venue is proper in this District because PTC agreed in the Collaboration Agreement § 15.6(b) that “any claim [or] dispute ... arising under or relating to this Agreement shall be brought exclusively in a court of competent

jurisdiction, state or federal, located in New York, New York ... and each party hereby consents to personal jurisdiction in ... such courts.”

### **GOVERNING LAW**

12. Pursuant to § 15.6(a) of the Collaboration Agreement, “any claim [or] dispute ... arising under or relating to this Agreement shall be governed by and construed under the laws of New York.” Accordingly, this action is governed by New York law.

### **FACTUAL ALLEGATIONS**

#### **A. The Collaboration Agreement**

13. On July 23, 2021, PTC pledged its financial support for a Study of CDD by becoming a signatory to the Collaboration Agreement. CDD is an exceedingly rare neurological condition, with an incidence rate of “1 in 40,000 to 60,000 newborns.”<sup>2</sup> A true and correct copy of the Collaboration Agreement is annexed hereto as Exhibit A.

14. The express purpose of the Collaboration Agreement is to plan, fund, and execute the Study evaluating the “feasibility and suitability ... of neurocognitive tests and functioning scales in the CDD population...” Collaboration Agreement, Exhibit A (“**Research Plan and Cost Estimate**”). The Study was to be overseen by a Steering Committee, defined by Section 1.26 of the Collaboration Agreement as “the individuals nominated by each of the Parties [to the Agreement],” including PTC, “in accordance with Section 3.4 to supervise the conduct of the

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<sup>2</sup> MedlinePlus, *CDKL5 Deficiency Disorder*, available at <https://medlineplus.gov/genetics/condition/cdkl5-deficiency-disorder/#:~:text=Frequency&text=CDKL5%20deficiency%20disorder%20appears%20to,CDKL5%20deficiency%20disorder%20are%20girls>.

Study.” Along with supervision, the Steering Committee’s responsibilities include “review[ing] and approv[ing] the Research Plan.” Collaboration Agreement § 3.4.2(a).

15. LLF’s role was to serve as sponsor of the Study and provide “overall leadership, management, and operational support for the Study.” Collaboration Agreement § 3.3.

16. The Research Plan and Cost Estimate includes an overview of the Study’s procedures and goals. Among other high-level generalities, the Research Plan and Cost Estimate states that the Study will include “up to 100 patients with a diagnosis of CDD.” Nowhere in the Collaboration Agreement is there any requirement or obligation on LLF’s part to meet this (or any other) patient enrollment threshold. *See* §§ 3.3.1(a)-(h) of the Collaboration Agreement.

17. In exchange for providing funding, PTC was to receive access to the Study Data, defined by the contract as including all “information ... inventions, [and] developments...” that are “conceived ... [or] developed in the conduct of the Study (the “**Study Data**”).” Collaboration Agreement §§ 5.1.1(a), (b), 1.32. The Study Data could then be used by PTC “for any internal or regulatory purposes ... required in connection with the research, development, and commercialization of its own product candidates.” *Id.* at § 6. Additionally, each Pharmaceutical Company would receive a “fully paid-up” and “irrevocable” license to “use and practice the Study Intellectual Property for the research, development, or commercialization of any diagnostic, therapeutic, or prophylactic.” *Id.* at § 8.2.

18. With respect to funding, the Collaboration Agreement states that “[e]ach ... Pharmaceutical Company,” including PTC, “shall pay to LLF the contributions to the Study set forth on Exhibit B at the times set forth on Exhibit B...” Collaboration Agreement § 3.2.2.

19. In addition to the initial payment of \$2,400,000 to be paid upon execution of the Collaboration Agreement, payments of \$1,700,000 in the aggregate on each of January 15, 2022,

July 1, 2022, July 1, 2023 and July 1, 2024 were required to be paid in equal amounts by the Pharmaceutical Companies. Collaboration Agreement, Exhibit B (“**Funding Commitment**”). PTC’s share of the annual payments was thus \$242,857.41. PTC made its share of the payments due upon execution and in January and July 2022.

20. LLF acted in reliance on PTC’s pledge to satisfy its Funding Commitment when it entered into the Collaboration Agreement and helped design and implement the Study.

#### **B. PTC’s Breach and LLF’s Demand for Payment**

21. Even before the July 1, 2023 payment became due, PTC sought to be released from its continuing obligations under the Collaboration Agreement. During a June 2, 2023 meeting with LLF, PTC requested that it be released from the Collaboration Agreement, citing internal layoffs and personnel departures. LLF refused and informed PTC that the July 1, 2023 payment remained due.

22. On June 30, 2023, PTC wrote to LLF (copying each of the Pharmaceutical Companies) informing LLF that “PTC intended to end its participation in the above-referenced Agreement.” In that same letter, PTC purported to provide “90-days’ notice of termination of PTC’s participation” and offered to make “one final *pro rata* payment equal to 90 days of PTC’s annual commitment for the current year, or \$59,882.58, in exchange for the full release of all claims.” Notably, nowhere in PTC’s June 30 letter to LLF is there any mention that LLF has not satisfied its obligations under the Collaboration Agreement. LLC did not accept PTC’s offer to make this reduced payment.

23. On July 14, 2023, counsel for LLF transmitted a letter by email to PTC informing PTC that it is in breach of contract for its failure to make the July 1, 2023 payment. In the letter, LLF reiterated to PTC that it “remains fully obligated to continue its agreed upon financial

support through July 1, 2024 as provided for in the Collaboration Agreement.” On or about July 23, 2023, representatives of PTC and LLF met to further discuss PTC’s non-payment. Once again, LLF reiterated to PTC that it fully expected the latter’s full financial commitments through 2024 to be met.

### **C. PTC’s Pretextual Termination**

24. After its efforts to induce LLF to release it from its contractual obligations were not successful, PTC then changed course. On August 4, 2023, in a pretextual effort to justify its non-payment and extract itself from the Collaboration Agreement, PTC informed LLF in a letter that PTC “has terminated its involvement in the ... Collaboration Agreement pursuant to Section 10.4 thereof, effective immediately... PTC has determined that the LouLou Foundation is in material breach of the Collaboration Agreement given that it has failed to adequately uphold and fulfill its responsibilities and obligations as Sponsor as defined under the Collaboration Agreement, and cannot be expected to uphold and fulfill them within the remaining Term.”

25. PTC attempted to justify its purported termination by stating that “patient recruitment in the CANDID Study ... is woefully behind schedule and is at risk of failing to reach the previously set goal of 100 patients enrolled by the end of October of this year.”

26. However, this justification is entirely pretextual. The enrollment status of the CANDID Study does not provide a valid basis for PTC’s termination of the Collaboration Agreement for several reasons.

27. First, Section 10.4 of the Collaboration Agreement permits termination by the Pharmaceutical Companies only where there has been material or repeated non-compliance with applicable laws or a material breach by LLF, neither of which has occurred. LLF is not responsible, nor has it ever been responsible for, patient enrollment. Rather, the Steering

Committee, comprised of individuals nominated by all parties, is tasked with “supervis[ing] the conduct of the Study.” Collaboration Agreement § 1.26. Moreover, the text of Exhibit A states, unambiguously, that the Study would enroll “*up to* 100 patients with a diagnosis of CDD” (emphasis added). A plain reading of this provision does not establish 100 patients as a mandatory minimum nor does it set the end of October 2023 as the Study enrollment deadline. On the contrary, 100 patients is the *maximum* number of patients to be enrolled. Because there is no binding contractual requirement to enroll 100 patients and no duty or obligation imposed on LLF to reach any such threshold, the Study enrollment status cannot serve as a viable justification for PTC’s purported termination.

28. PTC’s August 4, 2023 letter was sent to representatives of each of the other Pharmaceutical Companies.

#### **D. PTC’s Continuing Breach**

29. In its correspondence with PTC, LLF has explained that the purported termination is invalid and made continued demands to PTC for payment. Most recently, on August 30, 2023, LLF demanded that payment of \$485,714.82 for the amount of PTC’s 2023 and 2024 funding commitments be made no later than September 6, 2023. Those demands were reiterated in a call between LLF’s counsel and PTC the following day, and were ignored. To date, PTC has failed to pay any portion of its share of the 2023 and 2024 funding commitment. Each of the other Pharmaceutical Companies has paid its share of the funding payment due in July 2023.



**CAUSES OF ACTION**

**COUNT 1**

**Breach of Contract - July 2023 Payment**

30. LLF incorporates and realleges the foregoing paragraphs by reference as though fully set forth herein.

31. To make out a viable claim for breach of contract under New York law, a “complaint need only allege (1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages.” *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 177 (2d Cir. 2004) (quoting *Harsco Corp. v. Segui*, 91 F.3d 337, 348 (2d Cir. 1996)). Each element is satisfied in the present case.

32. As previously established, the Collaboration Agreement is a valid contract between LLF and the Pharmaceutical Companies, including PTC.

33. From the commencement of the Collaboration Agreement through the present, LLF has fully performed its obligations under the Collaboration Agreement. As explained above, PTC’s claim that LLF is in material breach is unavailing.

34. PTC remains obligated to make its share of the payment due on July 1, 2023.

35. Despite repeated demands from LLF, PTC has not made its portion of the payment due on July 1, 2023. As a result, PTC remains in breach of the Collaboration Agreement.

36. LLF has been damaged by PTC’s non-payment.

37. LLF is entitled to all damages, including attorney’s fees, as a result of PTC’s

breach.

## COUNT 2

### Breach of Contract - July 2024 Payment

38. LLF incorporates and realleges the foregoing paragraphs by reference as though fully set forth herein.

39. Anticipatory repudiation occurs when, “before the time for performance has arisen, a party to a contract declares [its] intention not to fulfill a contractual duty.” *Lucente v. Int'l Bus. Machines Corp.*, 310 F.3d 243, 258 (2d Cir. 2002). “When confronted with an anticipatory repudiation, the non-repudiating party ... may elect to treat the repudiation as an anticipatory breach and seek damages for breach of contract...” *Id.*

40. PTC’s August 4 letter and purported termination of the Collaboration Agreement constitutes a clear and unequivocal statement by PTC that it will not fulfill its contractual obligation to make the payment due on July 23, 2024. *See Safka Holdings LLC v. iPlay, Inc.*, 42 F. Supp. 3d 488, 492 (S.D.N.Y. 2013) (holding that a letter “expressing a clear unilateral intention not to fulfill Defendant’s obligations” constituted anticipatory repudiation).

41. As explained above, PTC does not have any valid basis to unilaterally terminate the Collaboration Agreement, as LLF has not committed a material breach. PTC’s August 4

letter therefore constitutes an anticipatory repudiation, which entitles LLF to recover the amounts that would otherwise become due in July 2024. *Lucente*, 310 F.3d at 258.

42. Despite LLF's demands, PTC has not made its portion of the payment due on July 1, 2024. As a result, PTC remains in breach of the Collaboration Agreement.

43. LLF has been damaged by PTC's non-payment.

44. LLF is entitled to all damages, including attorney's fees, as a result of PTC's breach.

### **COUNT 3**

#### **Breach of the Implied Covenant of Good Faith and Fair Dealing**

45. LLF incorporates and realleges the foregoing paragraphs by reference as though fully set forth herein.

46. Implied in all contracts governed by New York law is a covenant of good faith and fair dealing. The implied covenant of good faith and fair dealing provides that a party shall not do anything that will have the effect of interfering with or damaging the right of another party to receive the benefits of the contract.

47. At all times, PTC owed a duty to LLF to act in good faith and deal fairly with it under the Collaboration Agreement.

48. Here, Defendant's misconduct exceeds that causing its breach of contract. PTC is fully aware of its contractual obligations to LLF and the Study. After LLC refused to release

PTC from its contractual commitments, PTC, acting in bad faith, manufactured a pretextual justification to terminate the Collaboration Agreement.

49. Furthermore, PTC shared its pretextual justification to terminate the Collaboration Agreement with the other Pharmaceutical Companies, in a transparent effort to undermine and interfere with LLF's relationship with the other Pharmaceutical Companies.

50. PTC breached its covenant to act in good faith and deal fairly with LLF under the Collaboration Agreement.

51. Plaintiff LLF is entitled to compensation for Defendant PTC's breach of the implied covenant of good faith and fair dealing.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff LouLou Foundation demands judgment against Defendant PTC Therapeutics, Inc. as to the counts of the Complaint stated against it for:

- A) Compensatory damages in the amount of \$485,714.82 plus interest from the date of the breach in favor of Plaintiff against Defendant for all damages sustained as a result of Defendant's breach of contract and additional damages for Defendant's breach of the implied covenant of good faith and fair dealing;
- B) Plaintiff's reasonable attorney's fees, costs, and expenses incurred in this action;
- C) Such equitable relief/injunction or other relief as the Court may deem appropriate; and
- D) Such other and further relief as may be just and proper.

#### **JURY DEMAND**

Plaintiff LouLou Foundation hereby demands a trial by jury of any and all issues so triable, pursuant to Rule 38 of the Federal Civil Rules of Civil Procedure.

DATED: New York, New York  
September 26, 2023

**QUINN EMANUEL URQUHART &  
SULLIVAN, LLP**

By: /s/ Dennis H. Hranitzky  
Dennis H. Hranitzky  
2755 E. Cottonwood Parkway, Suite 430  
Salt Lake City, Utah 84121  
Tel: 801-515-7300  
Fax: 801-515-7400  
dennishranitzky@quinnemanuel.com

Debra D. O’Gorman  
51 Madison Avenue, 22nd Floor  
New York, NY 10010  
Tel: 212-849-7000  
Fax: 212-849-7100  
debraogorman@quinnemanuel.com

*Attorneys for Plaintiff*